O.K. 10/9/97

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Nashville District Office

297 Plus Park Boulevard
Nashville, TN 37217

October 9, 1997

CERTIFIED-RETURN RECEIPT REQUESTED

Henry Born, M.D.
Program Sponsor
Calhoun Treatment Center, Inc.
118 Choccolocco Street
Oxford, AL 36203

WARNING LETTER - 98-NSV-04

Dear Dr. Born:

On August 11-14, 1997, Food and Drug Administration (FDA) Investigator Patricia S. Smith inspected Calhoun Treatment Center, Inc., located at the above address.

Our review and evaluation of the investigator's report revealed the following significant violations of the Narcotics Treatment Program Standards, 21 CFR 291.505, Conditions for the Use of Narcotic Drugs:

1. Failure to have adequate equipment to provide medical services for admission in that the facility lacked an examination table to conduct physical examinations. [21 CFR 291.505(c)(3)]

2. Serological test for syphilis and tuberculin skin test were not routinely done as part of the admission physical examination prior to dosing. [21 CFR 291.505(d)(3)(i)]

3. The Medical Director failed to assure that the initial dose of methadone did not exceed 30 mg for patient No. 197. [21 CFR 291.505(d)(6)(i)(A)]

4. The program physician failed to approve a change in the dosage schedule for patient No. 197. [21 CFR 291.505(d)(6)(i)(B)]

5. You failed to provide and/or document counseling on preventing exposure to and transmission of HIV disease for twenty of the twenty-one patients whose records were reviewed. [21 CFR 291.505(d)(4)(i)(C)]

6. Failure of the Program Physician to sign annual reviews of treatment plans in twenty of the twenty-one patient files whose records were reviewed. [21 CFR 291.505(d)(3)(v)(C)]

7. Failure of treatment plans to include the name and reason for prescribing medication for emotional or physical problems. [21 CFR 291.505(d)(3)(iv)(A)(1)]

8. Failure to assure that the Program Physician fully informed each female patient of the possible risk to a pregnant woman and her unborn child from the use of LAAM administered in maintenance treatment. Patient No. 039 failed to complete the section of the Consent to Treatment for females of childbearing potential. [21 CFR 291.505(d)(4)(B)(3)]

The above noted violations are not intended to be an all-inclusive list of violations. It is your responsibility as sponsor to ensure that your program remains in compliance with all federal and state laws and regulations.

We acknowledge receipt of your September 13, 1997 response to the Form FDA 483 which was issued to Wendy B. Sprayberry, Executive Director at the termination of the inspection. This response does address the areas of primary concern. However, the implementation of the changes and assurance of the continuing effectiveness of any corrections can only be substantiated by a future inspection.

Failure to effect prompt corrections of the noted violations, or any further violations of the requirements set forth in 21 CFR 291.505 may result in enforcement action without further notice.

Any further correspondence regarding the subject inspection or changes you intend to implement should be directed to the attention of Frank J. Jancarek, Compliance Officer, at the above letterhead address.

Sincerely,

Raymond K. Hedblad

Raymond K. Hedblad
Director, Nashville District

RKH/kl